

deleted text between brackets and added text being underlined. No new matter has been added by the above amendments. Entry and reconsideration are respectfully requested.

RESPONSE TO OBJECTION TO THE SPECIFICATION:

The specification is objected to as requiring corrections. The above Amendment inserts the appropriate U.S. practice headings to the specification, as requested, as well as directed changes. In addition, Applicants attach **Appendix A** to this Amendment showing the location of added and deleted paragraphs. No new matter has been introduced by these changes

RESPONSE TO REJECTIONS UNDER 35 U.S.C. § 112, ¶2

Claims 34 and 35 have been rejected under 35 U.S.C. § 112, ¶2, as being incomplete. The Examiner argues that these claims are incomplete in not reciting a method step whereby the step of “determining the amount of said labeled molecule” is correlated with the presence or amount of the “ drug molecule” in the sample.

The applicants have clarified claim 34 and 35 by providing clear antecedent support for the analyte being detected. Accordingly, applicants respectfully submit that their rejection is now moot and should be withdrawn.

RESPONSE TO REJECTION UNDER 35 U.S.C. § 102(b) AND UNDER 35 U.S.C. § 103(a)

Claim 27-35 have been rejected under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Mosbach (U.S. Pat. No. 5,110,833). The applicants respectfully traverse this rejection.

The applicants submit that the claimed invention is not anticipated or made obvious by

Mosbach. The Examiner alleges that Mosbach discloses artificial antibodies which are of the same composition as of the instant claims, but having a specific polymer size particle range of "less than 25 μm " which encompasses, and therefore anticipates the range of "less than about 5 microns" recited instant claim 27.

Anticipation of a claimed range can occur when an invalidating reference discloses: (1) a narrower range completely within the claimed range; (2) a specific value or values within the claimed range; or (3) a range that "touches" the claimed range. See Atlas Powder Co.v. Ireco, Inc., 190 F.3d 1342, 1346, 51 U.S.P.Q.2d (BNA) 1943, 1948 (Fed. Cir.1999)("when a patent claims a chemical composition in terms of ranges of elements, any single prior art reference that falls within each of the ranges anticipates the claim"), and In re Malagari, 499 F.2d 1297, 1300 (CCPA 1974) ("...since it is clear that the "touching" of the carbon ranges constitutes an anticipation under Nehrenberg, it is submitted that the present rejection under 35 USC 102 is proper and should be sustained.")¹

Mosbach does not disclose an antibody particle size range: (1) within the claimed range or (2) that touches the claimed range. Mosbach does not expressly provide any specific or working examples of a finite particle size value or values within the claimed range. Therefore, Mosbach cannot anticipate that claimed range. In addition, Mosbach does, as the Examiner notes, teach a broad particle size range that encompasses applicants' claimed particle size range. However, applicants' claimed range resides at the lowest quadrant of Mosbach claimed range. Mosbach discloses a particle size less than 25 μm , compared with applicants' less than 5 μm . The upper value of applicants' range and that disclosed by Mosbach are not so close as to possibly infer an anticipation. In addition, there is no teaching in Mosbach that would convey to one of ordinary skill in the art at the relevant time that Mosbach contemplated any particle having a size of 5 μm or less.

Examiner also suggests that criticality of polymer particle sizes of "less than about 5 microns" of the instant invention versus the broader range of less than 25 μm of the prior art has not been demonstrated and that the claimed invention would have been obvious because one of ordinary skill would have been motivated to modify the Mosbach artificial antibodies to arrive at the claimed invention. Applicants disagree. While Mosbach may disclose a broad size range, there is

clearly no suggestion that one of ordinary skill in the art would select the lowest 20% of that broad range. Applicants particle size was selected for administration to a mammal body and must not be more than 5 μm or the size of normal biological antibodies, most preferred 10-100 nm. Because Mosbach only discloses the separation of antigen-selective polymers in an incubation mixture by filtration or sedimentation, one of ordinary skill in the art would not taught to select an antibody particle size that would be suitable for human administration. Therefore, it is respectfully submitted that Mosbach does not suggest the presently claimed invention.

RESPONSE TO REJECTION BASED ON NON-STATUTORY DOUBLE PATENTING

Claim 27-35 have been rejected under the judicially created doctrine of double patenting. Upon allowance of the Claims an appropriate terminal disclaimer will be filed. This rejection should be withdrawn.

CONCLUSION

In view of this Amendment, a timely Notice of Allowance is respectfully requested and the Applicant invites the Examiner to contact the undersigned if there are any remaining points at issue.

¹ In re Nehrenberg, 47 CCPA 1159, 280 F.2d 161 (1960).

Serial No.: 09/305,738

Docket No.: 2324-7028US1

AUTHORIZATIONS

The Commissioner is hereby authorized to charge any additional fees which may be required for the timely consideration of this amendment, or credit any overpayment to Deposit Account No. 13-4503, Order No. 2324-7028US1: A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

Respectfully submitted,

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APPENDIX A.

34. (twice amended) A method for assaying a drug molecule in a fluid, said method comprising the combination of steps:

- 1) providing a fluid sample with [said] a drug molecule,
- 2) adding a known amount of labeled drug molecule to said sample,
- 3) contacting said sample of step 2) with artificial antibodies according to claim 27[, whereby] so that said drug molecule and said labeled drug molecule [are] in said sample of step 2) competitively [bound to] bind with said artificial antibodies, and;
- 4) determining the amount of said labeled drug molecule unbound in said sample or bound to said artificial antibody so as to determine the amount of said drug molecule in said fluid.

35. (amended) The method according to claim 34, wherein said labeled drug molecule includes a label[, wherein said label is] selected from the group consisting of radioligands, enzymes, biotin, steroids, fluorochrome, electrochemiluminescent compounds, and gold

36. The artificial antibodies according to claim 27, wherein said particle size is between about 10 nm and 1000 nm.

37. The artificial antibodies according to claim 34, wherein artificial antibody size is between about 10 nm and 100 nm.

38. The artificial antibodies according to claim 34, wherein artificial antibody size is between about 10 nm and 1000 nm.

APPENDIX B.

Insert to page 4, between lines 6 and 7:

--BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1. Example benzodiazepine structures.

Figure 2. Polymerisation of functional monomers in the presence of a print molecule.

page 3, line 3

(see Figure 2 [Scheme 1]). Subsequent removal of the print molecule

page 9, between lines 7 add 8, add;

Figure 1.

page 11, line 3;

The preparation follows the reaction of [Scheme 1] Figure 2.

page 11, line 16.

The wavy lines in [Scheme 1] Figure 2 represent an idealised